## REMARKS

The present communication responds to the Office Action dated October 4, 2004. In that Office Action, the Examiner rejected claims 9-20 as being unpatentable over U.S. Patent 5,968,011 (Larsen et al.) in view of U.S. Patent 6,056,718 (Funderburk et al.) and U.S. Patent 5,522,803 (Teissen-Simony). In this response, claim 9 has been amended to recite that the cannula housing further includes a second passage for receiving a piercing needle wherein the piercing needle may be inserted through the passage in the cannula housing when the needle holder is secured to the cannula housing. Additionally, dependent claims 28 and 29 have been added.

The Examiner's rejection is traversed at least because none of the cited references disclose a catheter head including a needle holder comprising a guide sleeve axially surrounding a connecting needle and a cannula housing, the cannula housing including a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage, the cannula housing further including a passage for receiving a piercing needle wherein the piercing needle may be inserted through the passage in the cannula housing when the needle holder is secured to the cannula housing.

*Rejection under 35 U.S.C. § 103*

Claims 9-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Larsen et al. in view of Funderburk et al. and Teissen-Simony. This rejection is traversed at least for the following reasons.

**U.S. Patent 5,968,011**

The Examiner asserted that Larsen discloses a cannula housing, a cannula extending from the cavity, a retaining body secured within the cavity and in cooperation with the internal surface to locate the flange within the cavity, and a needle holder.

What Larsen et al. actually discloses is a subcutaneous injection set having a base element 1, a top element 2, a needle hub 3 with an insertion needle 14 and connector means 4 comprising a hose 5 for connecting the injection set to further parts of the infusion set. *Larsen et*

*al., Column 4, lines 35-39.* Larsen et al. does not disclose, teach or suggest a connecting needle. In fact, Larsen et al. specifically teaches that it advantageously does not have a connecting needle:

> Since there is no longer a need for a septum, a needle on the means for delivering the medication or therapeutic fluid can also be omitted. This means that the manufacturing has been significantly simplified and production costs have been decreased. *Larsen et al., Column 2, lines 22-27.*

Thus, at least, Larsen et al. does not disclose a connecting needle, as recited by independent claim 9. Further, Larsen et al. thus does not disclose a needle holder comprising a guide sleeve axially surrounding a connecting needle or a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage.

The Examiner conceded that Larsen et al. does not disclose a guide extending from the cannula.

**U.S. Patent 6,056,718**

While the Examiner conceded that Larsen et al. does not disclose a guide extending from the cannula , he argued that the use of guides extending from cannulas is conventional in the art, as evidenced by Funderburk et al.. The Examiner asserted that Figure 4 of Funderburk et al. shows a guide extending from a cannula and cooperating with a guide sleeve to position the connecting needle into a passage. The Examiner concluded that it would be obvious to modify the injection set of Larsen et al. with a guide extending from the cannula.

Claim 9 of the present application requires "a needle holder comprising a guide sleeve axially surrounding a connecting needle" and "a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage." Figure 4 of Funderburk et al. illustrates a cannula housing 14. The applicants thus assume that the Examiner cites Funderburk et al. for teaching "a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage."

Funderburk et al. discloses a medication infusion set. The Funderburk et al. infusion set comprises a three-part system including a cannula housing 14, an infusion hub 20 and an inserter

hub 16. The infusion hub 20 and the inserter hub 15 are interchangeable with the cannula housing 14. Figure 4 of Funderburk et al. shows a needle guide 34:

> In the preferred form, the proximal end of the cannula 12 is press-fit mounted onto a downstream end of a needle guide 34 formed from stainless steel or the like, and these assembled components are compression fitted into the bore 30 ... The upstream end of the needle guide 34 is flared outwardly to form a radially enlarged and generally conical seat for receiving and supporting a resilient self-sealing septum 36 in the form of a ball. *Funderburk et al., Column 4, lines 54-65.*

The needle guide 34 alternately receives an insertion needle 18 from an inserter hub 16 and an infusion needle 22 from the infusion hub 20:

> The insertion needle 18 is adapted to pierce the ball-shaped septum 36 and to extend through the needle guide 34 and further through the soft cannula 12, to position the sharp tip 50 at least slightly beyond the distal end tip of the cannula. *Funderburk et al., Column 5, lines 26-30.*

Because the needle guide 34 receives both the insertion needle 18, which must extend beyond the distal end tip of the cannula, and the infusion needle 22, which desirably does not extend to the cannula, special geometry is required:

> A forward or tip end of the infusion needle 22 protrudes outwardly from a distal face 80 of the infusion hub 20, with a length sufficient to extend through the resilient septum 36 and partially into the metal needle guide 34 within the cannula housing 14, when the infusion hub is connected to the cannula housing. Accordingly, with this geometry, the infusion needle 22 does not protrude beyond the needle guide 34 into the soft cannula 12, thereby minimizing or eliminating risk of needle-caused damage to the soft cannula. *Funderburk et al., Column 6, lines 47-56.*

Thus, a particular configuration is required to allow both the infusion hub 20 and the inserter hub 16 to be interchangeably connected to the cannula housing 14.

Due to the interchangeability of the inserter hub 16 and infusion hub 20 with the cannula housing 14, Funderburk et al. does not disclose or suggest a cannula housing having a passage for receiving a piercing needle wherein the piercing needle may be inserted through the passage in the cannula housing when the needle holder is secured to the cannula housing, as recited by claim 9, as amended. As stated at least at page 5 of the present application:

> Owing to the fact that a piercing needle need not be retracted from the passage channel, into which the connecting needle is introduced after placing the cannula and fixing the cannula housing, complete precharging of the catheter head up to the cannula, i.e. priming, is possible in the state of the cannula housing and the needle holder being connected. *Application, page 5.*

Because of the interchangeability discussed above, Funderburk et al. does not teach a configuration having this advantage.

Figure 4 of Funderburk et al. shows a mating slot 28 for receiving a protective shroud plate 26 of an infusion hub 20:

> In accordance with one primary aspect of the invention, the shroud plate 26 extends from the distal face of the infusion hub 20 to closely overlie and protect the infusion needle. As shown, the shroud plate 26 comprises a multi-faceted and preferably three-sided structure extending over the top and both sides of the infusion needle 22, and projecting from the infusion hub at least slightly beyond the distal end tip of the infusion needle ... Moreover, the protective shroud plate 26 presents a keyed structure for unidirectional or one-way connection of the infusion hub 20 with the cannula housing 14, in a manner providing a strong interconnection with accurate guided coupling of the infusion needle 22 through the septum 36 and into the needle guide 34, yet additionally permitting quick and easy disconnection when desired. Specifically, the shroud plate 26 is sized and shaped for slide-fit reception into the matingly shaped and thus preferably three-sided slot 28 formed in the proximal face 42 of the cannula housing 14, to extend over the top and at both sides of the retainer clip 38. *Funderburk et al., Column 7, lines 8-21.*

The mating slot 28 does not comprise a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage.

**U.S. Patent 5,522,803**

The Examiner further cited Teissen-Simony as proving the conventionality of guides in infusion sets. The Examiner asserted that Figure 8 of Teissen-Simony shows guides (15, 16) extending from a cannula to guide the connecting needle.

Teissen-Simony discloses an infusion set. Teissen-Simony comprises a three-part system including a cannula housing 1, a connecting hub 3 and an inserter needle hub 41. The connecting hub 3 and the inserter needle hub 41 are interchangeable with the cannula housing 1.

Figure 8 of Teissen-Simony illustrates a cannula housing. The cannula housing includes guide openings 15 and 16 for receiving guide pins 21 and 22 of a connecting hub 3:

> As illustrated in FIGS. 6 to 10, the cannula housing comprises two guide openings 14 (sic) and 15 and two locking openings 17 and 18 in addition to the rectilinear through bore 10. These openings are symmetrically shaped about a plane including a central axis 14 of the through passageway 13 and extending perpendicular to the rear side 6. The guide openings 15 and 16 are elongated openings of a substantially square cross section, cf. FIGS. 6, 8, and 10, which are adapted to receive mating guide pins 21 and 22 on the connecting hub 3, cf. FIG. 13. *Teissen-Simony, Column 4, lines 57-66.*

The guide openings 15 and 16 of Teissen-Simony do not comprise "a guide extending from the cannula housing and cooperating with the guide sleeve to position the connecting needle into the passage" wherein the guide sleeve of the needle holder axially surrounds a connecting needle. As seen in Figure 13, there is no structure surrounding the needle 40 of the connecting hub 3. The guide pins 21 and 22 are spaced from the needle 40:

> When inserted through the membrane 12 in the cannula housing 1, this needle provides a connection between the hose 4 of the infusion set and the through passageway 13 of the cannula housing 1. As illustrated in FIG. 13, the length of the guiding pins 21 and 22 is longer than the freely projecting portion of the needle 40 with the result that during the coupling to the cannula housing 1 the connecting hub 3 is placed with the needle 40 in a centered position relative to the membrane 12 before said needle 40 is inserted through said membrane. In this manner it is ensured that the needle 40 is not damaged during the coupling procedure. *Teissen-Simony, Column 6, lines 18-29.*

Thus, Teissen-Simony does not teach or suggest a needle holder comprising a guide sleeve axially surrounding a connecting needle nor a needle guide extending from the cannula housing and cooperating with the guide sleeve, as recited by claim 9.

Further, due to the interchangeability of the connecting hub 3 and the inserter needle hub 41 with the cannula housing 1, Teissen-Simony does not disclose or suggest a cannula housing having a passage for receiving a piercing needle wherein the piercing needle may be inserted through the passage in the cannula housing when the needle holder is secured to the cannula housing, as recited by claim 9, as amended.

*Conclusion*

For at least the reasons discussed above, claims 9-20, along with new claims 28 and 29 are allowable over the combination asserted by the Examiner.

It is believed that no additional claim fees are due in connection with this communication. However, a petition to extend the time to respond is being submitted herewith, and the Office is hereby authorized to charge any deficiency or credit any overpayment associated with this communication or the petition to Deposit Account 04-1420.

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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